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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Michael D. DeGould

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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

02/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/640,366	Applicant(s) DEGOULD, MICHAEL D.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-14, 16-20 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-14, 16-20 and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the amendment filed October 2, 2008. All rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 102 – Anticipation (Previous Rejection)

1) Claims 12-13 and 18 were rejected under 35 U.S.C. 102(b) as being anticipated by Berggren et al. (US 5,620,700). The rejection is maintained.

Applicant's Arguments

Applicant argues the reference discloses the solutions are unlike gels or solutions, or other fluids. Thus, in the biological pocket, the Berggren material is unlike gels. It is noted that The American Heritage Dictionary of the English Language, Fourth Edition, 2006 defines unlike as "Not alike; different". Thus, below 38 degrees Celsius, the Berggren material is different from a gel. In contrast, amended claim 12 states that the dressing is a gel at body temperature. Thus, the Applicant's claimed invention is substantially different than what is disclosed in Berggren.

Examiner's Response

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Although the reference discloses the viscous compositions of the reference are unlike gels or solutions or other fluids, it may be reasonably concluded from the context of the disclosure that the term “gels” encompass liquid gels and not necessarily more viscous or semisolid to solid gels, especially considering the reference states “or other fluids” (col. 4, lines 48 and 49). Gels may also be semisolid (such as jelly) and solid formulations (as discussed in the previous office action), which would encompass “form of a more viscous, less- to non-flowable mass which will remain in the periodontal pocket when at the body temperature of the host animal” (col. 4, lines 19-22). It may be reasonably concluded that when a gel becomes more viscous or less flowable that it may still be considered a “gel”. Further, the reference also discloses substantially the same compositions, comprising a cross-linked collagen, as the instant claims and therefore should have substantially the same physical attributes as the compositions of the instant claims such as being a “gel at body temperature”. Therefore the rejection is maintained.

Claim Rejections - 35 USC § 103 - Obviousness (Previous Rejections)

1) Claims 1-2, 4-6, 8-9, 16, 19, 25-26 and 28-29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman (US 5,002,769) in view of Berggren et al. (US 5,620,700). The rejection is maintained and further applied to claims 12-13 and 18. Claim 29 is cancelled.

Applicant's Arguments

Applicant argues the implants of Friedman are a non-gel-like material. Thus, the Friedman dressing is not a gel. Berggren et al. discloses the solutions are unlike gels or solutions, or other fluids. Thus, in the biological pocket, the Berggren material is unlike gels. In contrast, amended claim 12 states that the dressing is a gel at body temperature. Accordingly, it is submitted that Berggren and Friedman do not teach or suggest all of the claim limitations of amended independent claim 1 or amended independent claim 12 (and claims 13-14 and 16-20 that depend thereon) or amended independent claim 25 (and claims 26-29 that depend thereon). Applicant submit that the proposed combination of Friedman with Berggren would change the principle of operation of Friedman such that the teachings of Friedman in view of Berggren are not sufficient to render amended independent claims 1 and 12 and 25 prima facie obvious. The sustained-release compositions of Friedman are formed through the solidification of a liquid precursor described herein as a 'liquid composition.' Therefore, the device of Friedman operates as a solid. In contrast, Berggren discloses a flowable material for the delivery of drugs. Thus, if one were to incorporate the flowable material of Berggren into Friedman, the principle of operation of Friedman, that is, the use of dried solid implants would be completely changed.

Examiner's Response

The motivation to use the flowable material of Berggren to treat the conditions of Friedman such as "dry socket" is to use a composition with a medicinal agents disclosed to treat the condition as disclosed by Friedman with the techniques disclosed

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by Friedman, not necessarily to achieve the same rate of release of the medicinal agent. By incorporating the solutions of Berggren into the oral cavity using the methods of Friedman, which include injecting the solution into the cavity and suturing the opening, the composition will conform more exactly to the size and shape of the pocket. It is reasonable to conclude that by doing so the composition will cover the entire area of a treatment to provide the active ingredient to the entire surface of the targeted area. As stated above, it may be reasonably concluded from the context of the disclosure that the term “gels” encompass liquid gels and not necessarily more viscous or semisolid to solid gels. Gels may also be semisolid (such as jelly) and solid formulations (as discussed in the previous office action), which would encompass “form of a more viscous, less- to non-flowable mass which will remain in the periodontal pocket when at the body temperature of the host animal”. It is reasonably concluded that when a gel becomes more viscous or less flowable that it may still be considered a “gel”.

2) Claims 7 and 17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman (US 5,002,769) in view of Berggren et al. (US 5,620,700) as applied to claims 1-2, 4-6 and 8-9 in further view of Miller et al. (US 6,509,031). The rejection is maintained.

Applicant's Arguments

See Applicant's Arguments above in regards to Friedman and Berggren. Miller was cited as teaching peroxides as a cross-linking agent. However, if one were to incorporate the material of Miller into Friedman, the principle of operation of Friedman,

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that is, the use of dried implants would be completely changed. Thus, a *prima facie* case of obviousness for amended independent claim 1 cannot be established using Miller.

Examiner's Response

See Examiner's response above in regards to Friedman and Berggren. In regards to Miller, the peroxides of Miller would act as the cross-linking agent in the compositions of Berggren in the methods of Friedman. Therefore the agent would not change the operation of Friedman and the peroxide would be used for its known function in the compositions of Berggren, which is supported by previously cited precedent. See MPEP 2144.07.

3) Claims 3, 10, 14 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman (US 5,002,769) in view of Berggren et al. (US 5,620,700) as applied to claims 1-2, 4-6, 8-9, 16, 19, 25-26 and 28-29 in further view of Higashi et al. (US 4,906,670). The rejection is maintained.

Applicant's Arguments

See Applicant's Arguments above in regards to Friedman and Berggren. Higashi was cited as disclosing a periodontal disease treatment comprising atelocollagen and a cross-linking agent. However, looking at Experiment 1 of Higashi, glutaraldehyde is used in forming the Higashi material, and as explained at page 2, lines 28-30 of the present specification, there are problems with using glutaraldehyde. Note that all of

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independent claims 1, 12, and 25 exclude glutaraldehyde which is cytotoxic. Thus, one would not look to Higashi to make up for the deficiencies in Friedman.

Examiner's Response

See Examiner's response above in regards to Friedman and Berggren. In regards to Higashi, the reference is used to disclose the benefits of using atelocollagen as a collagen derivative. Further the reference suggests other ways to cross link collagen. Further it discloses "chemical agents such as glutaraldehyde" (col. 3, lines 52-56), which may also encompass other agents. Therefore one of ordinary skill in the art would look to Higashi to determine an appropriate collagen to use in the compositions of Berggren.

Claims 1-10, 12-14, 16-20 and 25-28 are rejected.

No claims allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612